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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.								
10/576,803	04/21/2006	Mary J. Champion	D-3150	5915								
Frank J Uxa 4 Ventura Suite 300 Irvine, CA 92618	7590 04/05/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">GHALI, ISIS A D</td></tr><tr><td>ART UNIT</td><td>PAPER NUMBER</td></tr><tr><td>1615</td><td></td></tr></table>		EXAMINER		GHALI, ISIS A D		ART UNIT	PAPER NUMBER	1615	
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SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE									
3 MONTHS		04/05/2007	PAPER									

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/576,803

Applicant(s)

CHAMPION, MARY J.

Examiner

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,35,36,38,39,41,44,45 and 55-66 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 33, 35, 36, 38, 39, 41, 44, 45, 55-66 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The receipt is acknowledged of applicant's preliminary amendment filed 04/21/2006, and supplemental preliminary amendment filed 03/27/2007.

Claims 1-32, 34, 37, 40, 42, 43 and 46-54 have been canceled.

Claims 55-66 have been added.

Claims 33, 35, 36, 38, 39, 41, 44, 45, 55-66 are pending and included in the prosecution.

Information Disclosure Statement

1. The mentioning the references in the specification is not a proper information disclosure statement. Unless the references have been cited by the examiner on form PTO-892, they will not be considered. Under 37 CFR 1.98(a)(1), it is required: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be

considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement.

Specification

2. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 39, 60 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expressions "at least partially" and "substantially free of the water containing gel" do not set out the metes and bounds of the claims. Recourse to the specification does not define the expressions.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 33, 35, 36, 38, 41, 44, 45, 55-59, 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over the presentation prepared by Kobayashi Healthcare, INC.: "Product Concept Test", hereinafter Kobayashi, in view of any of JP 2002119529 ('529) or US 6,224,899 ('899).

Kobayashi article disclosed cooling gel sheet used for treating hot flashes. The article implies that the gel sheets been in use before the article date August 14, 2003. hot flashes are known as symptoms associate the menopause syndrome. The article does not teach any active agent in the gel sheet.

Kobayashi article does not teach instructing the user to apply the cooling gel sheet at a location on specific site as claimed by claims 33, 44, 45, 55 and 61. Kobayashi article does not teach structure of the cooling device as comprising water containing gel comprising polyacrylic component and gas permeable substrate as claimed by claims 35, 36, 38, 57-59, 63-65, or the package are claimed by claims 56 and 61.

Regarding the instruction, it is not patentable limitation in utility application. The instruction to apply the patch at specific site does not impart patentability to the claims because it is expected that the patch will be applied to the site of origin of hot flashes as disclosed by applicant on page 9, lines 1-5. With regard to the package, the package does not impart patentable weight absent functional relationship between the package and the product, and because the product still function equally effectively with or without the package.

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JP '529 teaches cooling patch which can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay, said patch comprises water permeable film covered with hydrous paste of polyacrylic acid (abstract; paragraphs 0004-0008).

US '899 teaches adhesive cooling gel contains large amount of water spread on moisture permeable sheet (abstract; col.8, lines 61-66). The adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue (col.1, lines 53-55, 59-61). The cooling patch can be applied locally to the area of discomfort without limitation to the body part such as fever, inflammation, pain or sprain to assuage the discomfort (col.8, lines 41-58).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling gel sheet to treat hot flashes as disclosed by Kobayashi article, and made the sheet of hydrous material comprising polyacrylic acid on a water permeable sheet as disclosed by JP '529 or US '899, motivated by the teaching of JP '529 that such a cooling patch structure and materials can maintain the cooling effect while being able to cool the affected part at an early stage and can maintain a cooldown delay, or motivated by the teaching of US '899 that such an adhesive cooling gel is stable and is excellent in cooling effect and/or coolness-preserving effect on human skin and can be removed from the skin without leaving any residue, with reasonable expectation of having cooling patch or sheet comprising water permeable backing and polyacrylic acid paste or gel that is able to maintain the cooling

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effect and preserve the coolness of the site of its application to treat hot flashes successfully and effectively.

7. Claims 33, 35, 36, 38, 41, 44, 45, 55-59, 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP '529 or US '899 each in view of US 5,730,957 ('957).

The teachings of JP '529 and US '899 are discussed above.

The references do not teach providing instruction the user as claimed by claims 33, 44, 45, 55 and 61, or the package as claimed by claims 56 and 61.

Regarding the instruction, it is not patentable limitation in utility application. The instruction to apply the patch at specific site does not impart patentability to the claims because it is expected that the patch will be applied to the origin site of hot flashes, as disclosed by applicant on page 9, lines 1-5. With regard to the package, the package does not impart patentable weight absent functional relationship between the package and the product, and because the product still function equally effectively with or without the package.

Although JP '529 and US '899 teach cooling devices applied at the site of pain or fever, the references do not explicitly teach treating hot flashes.

US '957 teaches cooling mixture used for cooling the body to treat medical conditions such as fever, to offer heat relief for those who experience hot flashes, and relief muscular strain (abstract; col.5, line 6 till col.6, line 18). Therefore, the art recognized using cooling technique to treat fever, hot flashes, and muscle stain equally.

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In other words, the art recognized the equivalency between fever, hot flashes, and muscle strain, in terms of treating them using the same cooling methods and devices.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to treat fever, muscle strain or pain using cooling devices comprising aqueous gel and permeable backing as disclosed by JP '529 or US '899, and further use such devices to treat hot flashes as disclosed by US '957, motivated by the teaching of US '957 that the cooling mixtures that treat fever and muscle strains will effectively offer heat relief for those who experience hot flashes, with reasonable expectation of having cooling devices comprising aqueous gel and permeable backing offering heat relief for those who experience hot flashes with great success.

8. Claims 39, 60, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of article by Kobayashi with of any of JP 2002119529 ('529) or US 6,224,899 ('899) and further in view of US 3,811,438 ('438).

The combines teachings of Kobayashi with either JP '529 or US '899 are discussed above.

However, the combined teachings of the references do not teach strips of adhesive located over the gel that is substantially free of adhesive as claimed by claims 39, 60 and 61.

US '438 teaches an adhesive bandage comprising a backing layer coated with continuous adhesive layer covered by strips of adhesive having less adhesiveness to

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provide bandage that readily removable with reduced pain or discomfort of the user (col.1, lines 45-49; co1.3, lines 65-68; co1.4, lines 1-3, 38-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling gel sheet to treat hot flashes comprising of hydrous material comprising polyacrylic acid on a water permeable sheet as disclosed by the combined teachings of Kobayashi article with JP '529 or US '899, and further add strips of less adhesiveness on/around the paste or gel as disclosed by US '438, motivated by the teaching of US '438 that such the presence of two adhesiveness of different adhesiveness strength provide bandage that readily removable with reduced pain or discomfort of the user, with reasonable expectation of having cooling gel patch to treat hot flashes having strips of adhesives with different adhesiveness strength that is readily removable with reduced pain or discomfort of the user.

9. Claims 39, 60, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of any of JP 529 or US '899 each with US '957, and further in view of US '438.

The combined teachings of JP '529 and US '899, each with US '957 are discussed above.

However, the combined teachings of the references do not teach strips of adhesive located over the gel that is substantially free of adhesive as claimed by claims 39, 60 and 61.

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US '438 teaches an adhesive bandage comprising a backing layer coated with continuous adhesive layer covered by strips of adhesive having less adhesiveness to provide bandage that readily removable with reduced pain or discomfort of the user (col.1, lines 45-49; co1.3, lines 65-68; co1.4, lines 1-3, 38-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a cooling gel sheet to treat hot flashes comprising of hydrous material comprising polyacrylic acid on a water permeable sheet as disclosed by the combined teachings of JP '529 or US '899 with US '957, and further add strips of less adhesiveness on/around the paste or gel as disclosed by US '438, motivated by the teaching of US '438 that such the presence of two adhesiveness of different adhesiveness strength provide bandage that readily removable with reduced pain or discomfort of the user, with reasonable expectation of having cooling gel patch to treat hot flashes having strips of adhesives with different adhesiveness strength that is readily removable with reduced pain or discomfort of the user.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,956,963 disclosed treatment of hot flashes using wrist cooler.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615



IG

ISIS GHALI
PRIMARY EXAMINER